

## **REMARKS**

### **1. Preliminary Remarks**

Claims 1 to 59 are currently pending. Claims 28 to 33 were the subject of a final rejection under 35 U.S.C. §102 as anticipated by Broder et al. U.S. Patent No. 5,968,972 ("Broder"). Claims 1-27 and 34 to 59 are withdrawn from consideration as being drawn to a nonelected invention. Applicant reserves the right to pursue claims 1-27 and 34-59 in one or more divisional or continuation applications.

### **2. Rejection Of Claims 28 To 33 Under 35 U.S.C. §102**

In the Office Action of January 15, 2004, the Examiner rejected claims 28 to 33 under 35 U.S.C. §102 as being anticipated by Broder. Applicant maintain that Broder does not anticipate claim 28 or its dependent claims because Broder does not suggest or teach amounts of opioid inhibitors in the range of 0.0001  $\mu\text{m}$  to 100  $\mu\text{m}$ . Applicant submits that the rejection is based on an improper and erroneous determination that the claimed amounts are inherent in the disclosure of Broder. Applicant also maintain that Broder does not suggest or teach that opioids such as naloxone, naltrexone, and nalmefene are PGP-inhibitors, for the reasons set forth in Applicant's response dated October 20, 2003.

In the Office Action of January 15, 2004, the Examiner stated that Applicant's arguments filed October 20, 2003, had been fully considered but were not persuasive. The Examiner stated:

Applicant asserts that Broder does not suggest or teach that opioids such as naloxone, naltrexone and nalmefene are inhibitors of P-glycoprotein and also does not suggest or teach amounts of opioid inhibitors in the range of 0.00001 (sic)  $\mu\text{M}$  to 100  $\mu\text{M}$ . **In reply, these properties are considered to be inherent.**

(Office Action dated January 15, 2004, page 2) (emphasis added). The Office Action does not contain any other discussion regarding the claimed amounts of opioid inhibitors in the range of 0.0001  $\mu\text{M}$  to 100  $\mu\text{M}$ .

Applicant respectfully submits that this determination of inherency is improper, since it is not supported by any evidence. Applicant also submits that this determination is erroneous, since the compositions in Broder do not necessarily have the claimed amounts of opioid inhibitors in the range of 0.0001  $\mu\text{M}$  to 100  $\mu\text{M}$ . Without this determination of inherency, there can be no anticipation of claims 28 to 33 by Broder.

The requirements for a determination of inherency are set forth in Section 2112 of the Manual of Patent Examining Procedure. The MPEP explains that, to be "inherent", a characteristic must necessarily be present in the prior art disclosure. "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." MPEP §2112, *citing In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). MPEP §2112 also states:

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) . . . .

MPEP §2112 (citations and parentheticals omitted).

In view of these requirements for a rejection based on inherency, Applicant respectfully submits that the determination of inherency in the Office Action of January 15, 2004, is not proper. The Office Action does not set forth any basis in fact or technical reasoning that supports a finding of inherency.

Moreover, it is improper to simply disregard numerical language as "inherent" and refuse to consider it in determining patentability. *In re Glaug*, 283 F.3d 1335 (Fed. Cir. 2002). In *Glaug*, the USPTO rejected claims as obvious, holding that a numerical

measure was inherent in the Applicant's claimed improvement and did not impart patentability. *Id.* at 1341. The Federal Circuit reversed this rejection, stating:

While the measurement of a physical property may not of itself impart patentability to otherwise unpatentable claims, when the measured property serves to point up the distinction from the prior art, that property is relevant to patentability, and its numerical parameters can not only add precision to the claims but also may be considered, along with all of the evidence in determination of patentability.

*Id.* at 1341. Similarly, in the present application, the claimed amounts of opioid inhibitor in claims 28 to 33 point up an important and unrecognized distinction from Broder.

The compositions of claims 28 to 33 comprise an opioid inhibitor of the ABC transporter protein in amounts of opioid inhibitors that range from 0.0001  $\mu\text{M}$  to 100  $\mu\text{M}$ , and those claimed amounts are effective for inhibiting ABC drug transporter protein. Broder nowhere suggests or teaches that the claimed amounts are effective for inhibiting ABC drug transporter protein. Moreover, nothing in Broder requires a composition having an opioid inhibitor in the range of 0.0001  $\mu\text{m}$  to 100  $\mu\text{m}$ . Accordingly, the claimed amounts are not necessarily present in Broder and therefore cannot be inherent in Broder.

Since the rejection is based on an improper and erroneous determination that the claimed amounts are inherent in the disclosure of Broder, the rejection of claims 28 to 33 under 35 U.S.C. §102 as being anticipated by Broder should be withdrawn.

### **3. Conclusion**

For the foregoing reasons, Applicant submits that the pending claims are not anticipated by Broder, U.S. Patent No. 5,968,972 and that the anticipation rejection may properly be withdrawn. Thus, claims 28-33 as amended herein are in condition for allowance.

Application No. 10/003,215  
Response and Request for Reconsideration dated April 15, 2004  
Responding to Office Action of January 15, 2004  
Examiner Donna A. Jagoe

The Examiner is invited to telephone Applicant's representative to discuss any questions or be of any assistance to the Examiner in the reconsideration and allowance of this case.

Respectfully submitted,

A handwritten signature in cursive script, reading "Michael B. Harlin", written in dark ink. The signature is positioned above a horizontal line.

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